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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,472	11/14/2003	Charles A. Vacanti	07917-082003	1928
23579	7590	08/14/2006	EXAMINER	
PATREA L. PABST PABST PATENT GROUP LLP 400 COLONY SQUARE SUITE 1200 ATLANTA, GA 30361			GAMETT, DANIEL C	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/713,472	Applicant(s) VACANTI ET AL.	
	Examiner Daniel C. Gamett, PhD	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43, 44 and 54-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43, 44, and 54-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/05/2006 has been entered.
2. Claims 43, 44, and 54-62 are under consideration.
3. All prior objection/rejections not specifically maintained in this office action are hereby withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

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with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 43 and 58-62 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21, 25-30, 47 of U.S. Patent No. 6171610. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. Claim '610-21 is drawn to a tissue forming structure comprising tissue precursor cells within a biocompatible support structure, wherein the tissue precursor cells are selected from the group consisting of central nervous system neural stem cells, autonomic nervous system neural stem cells, peripheral nervous system neural stem cells, neuroendocrine stem cells. Therefore, the tissue forming structure of claim '610-21 is equivalent to a mammalian adult undifferentiated cell population derived from neural, endocrine, or neuroendocrine tissue, in combination with a support structure for implantation, as recited in instant claim 1. Isolation cells by digestion of dissociated cells with a trypsin-like enzyme is necessarily taught in the 6171610 patent, as the present application is a continuation thereof. The tissue forming structure of claim '610-21 comprises a hydrogel (as in instant claim 58) and dependent claims '610-(25-30) recite metal, polymer, mesh, and hydroxyapatite materials, as in instant claims 58-61. Claim '610-47 recites a method of spinal cord repair using a tissue forming structure equivalent to that of claim '610-21, thereby rendering instant claim 62 obvious.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claim 43 and 58-62 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5776747, filed May 32, 1995, with priority from May 9, 1995. U.S. Patent 5776747 teaches (column 6, lines 14-36) that primary neural stem cells, astrocytes, oligodendrocytes, and their precursors (undifferentiated cells) may be used in “bioartificial organs”, a type of support material for implantation. The cited methods for derivation of primary cells employ trypsin (e.g. Richards *et al.*, PNAS 1992 89: 8591-8595). U.S. Patent 5776747, therefore, teaches all of the limitations of claim 43; claim 62 is also anticipated because an intended use cannot distinguish a product over prior art. The ‘747 patent further teaches that bioartificial organs comprise hydrogels (column 19, lines 41-48) and polymers (column 20, lines 1-10), and that growth factors may be co-encapsulated with the cells (column 14, lines 11-15), thereby anticipating claims 58-61.

9. The examiner notes that cells described only as “undifferentiated” and isolated by such common techniques as trypsinization and centrifugation will always be found to be anticipated or obvious over the prior art. The following passages of the instant specification may provide a

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basis for a product-by-process claim: Page 27, lines 16-22; page 44, lines 15-29; page 45, line 16-20; page 51, lines 4-12; page 52, lines 6-14. This suggestion is offered without making any predictions as to the patentability of any amended claims that may be submitted in the future.

Claim Rejections - 35 USC § 112

10. Claims 58-60 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's amendment to independent claim 43 without corresponding amendments to these dependent claims has introduced ambiguity regarding the recited additional structures. For example, it is not clear that the "hydrogel support structure" of claim 58 provides further limitation to the "support material for implantation" of claim 43 or it is meant to be an additional element altogether.

Conclusion

11. No claims are allowed.


DAVID S. ROMEO
PRIMARY EXAMINER

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Applicant's attention is directed to MPEP § 502.03, regarding the use of Internet e-mail. Subsection V states in part that, "Internet e-mail shall **NOT** be used to conduct an exchange of communications similar to those exchanged during telephone or personal interviews unless a written authorization has been given under Patent Internet Usage Policy Article 5 to use Internet e-mail. In such cases, a paper copy of the Internet e-mail contents **MUST** be made and placed in the patent application file...in the same manner as an Examiner Interview Summary Form is entered."

DCG

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10 August 2006